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Advancing New Claims Under the Lanham Act

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Implementing unique litigation tactics, on June 15, 2016, Par Pharmaceutical and related parties (Par as "Complainants") filed a complaint under Section 337 of the Tariff Act at the International Trade Commission ("ITC"). The complaint, which is grounded in allegations of the unlawful importation of certain Potassium Chloride powder products into the United States, sale for importation, and/or sale after importation, seeks a permanent limited exclusion order and a cease and desist order against Viva Pharmaceutical Inc., a Canadian company, Virtus Pharmaceuticals, LLC, a Florida-based company, and Virtus Pharmaceuticals OPCO II, LLC, a Tennessee-based company (collectively, "Virtus") (all together, "Respondents"), in addition to their respective agents and related companies. While 337 complaints alleging patent infringement, copyright infringement, and trademark infringement are common, this is the first 337 complaint based on the unfair act of a competitor's marketing of an unapproved drug.

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On July 21, 2016, the ITC issued a press release stating that it "voted to institute an investigation of certain potassium chloride powder products" in response to the June 15th complaint. The press release further specified each of the named Respondents as the subjects of the investigation (Inv. No. 337-TA-1013). On July 22, 2016, the ITC assigned the investigation to Administrative Law Judge MaryJoan McNamara. Judge McNamara will make an initial determination of the case as to whether Respondents violated Section 337 of the Tariff Act. Upon completion, the Commission will review Judge McNamara's decision.

The product at issue is a prescription medication for the treatment of prophylaxis of hypokalemia with or without metabolic alkalosis. Hypokalemia is a deficiency of potassium in the blood stream and it is potentially life-threatening when not treated. Although cases such as this typically invoke FDA jurisdiction under the FDCA, the Supreme Court, in *Pom Wonderful*,[1] ruled that the FDCA does *not* preclude a Lanham Act claim alleging unfair competition arising from false or misleading product descriptions. Rather, "the FDCA and the Lanham Act complement each other" in this area of the law.[2]

Par sells the only FDA-approved Potassium Chloride powder product on the market. However, despite this information, Respondents maintain, on average, a sixty-five percent hold on the market. The complaint alleges that this grasp on the market is due to Respondents' importation of the drug as a dietary supplement, when, in reality, Respondents sell the product as a prescription drug in the U.S. market. Complainants allege that this method of importation, and subsequent false labeling of the product, misleads consumers into purchasing Respondents' product, which ultimately harms Par, as well as the public interest.

The complaint further alleges that the disparity in the share of the market is due to Respondents' unfair competition of false and misleading advertising, packaging, marketing, promotion, distribution, and sale of the product. Complainants specify that the packaging fails to include a disclaimer that the product is not FDA-approved, that it contains an Rx symbol on the front of the packaging, appears like a legitimately approved product, and is listed as a legitimate and approved product on the websites of wholesale distributors, GPOs, IDNs, and price lists. Importantly, Respondents' product is listed alongside Complainants', giving the appearance to buyers and consumers that the products are interchangeable, if not identical. To bolster this representation, Virtus's website states that "[a]ll of the products at Virtus Pharmaceuticals follow strict FDA guidelines and

operating procedures," which Par alleges is literally false. These actions and statements, coupled with Respondents' unlawful importation of the Potassium Chloride powder product, constitute the grounds for Respondents' alleged violation of Section 43(a) of the Lanham Act (15 U.S.C. § 1125(a)).

With regard to injury, Par claims significant monetary investment costs in developing, obtaining approval for, purchasing equipment for, and manufacturing the Potassium Chloride powder product. In addition to these costs, Complainants state that the unlawful importation and subsequent false and misleading advertising of Respondents' product has caused and continues to cause substantial injury to the domestic industry.

This new 337 complaint is groundbreaking in its alleged unfair act of a competitor's marketing of an unapproved drug, and provides additional protection for pharmaceutical companies that face this type of unfair competition.

Kara Nunez, was a contributing author on this post.

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[1] Pom Wonderful LLC v. Coca-Cola Co., 134 S. Ct. 2228, 2233 (2014) ("There is no statutory text or established interpretive principle to support the contention that the FDCA precludes Lanham Act suits . . .").

[2] *Id.*